510(k) Summary

JUL 28 2011

Contact: Michelle McDonough
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Date Prepared: July 21, 2011

Device Trade Name: N-Force Fixation System

Manufacturer: Innovision, Inc.
1975 Nonconnah Blvd.
Memphis, TN 38132

Common Name: Smooth or threaded metallic bone fixation fastener

Classification: 21 CFR 888.3040

Class: II

Product Code: HWC

Indications For Use:
The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver the following bone void fillers to a surgical site:

- Beta-bsm (ETEX Corporation)
- CarriGen (ETEX Corporation)

Device Description:
The N-Force Fixation System is a screw system for fracture fixation. It includes fully and partially cannulated screws in various lengths, and accompanying instruments.

The N-Force Fixation System screws are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The N-Force Fixation System is cannulated and fenestrated which allow it to be used as a delivery system for ETEX Beta-bsm and ETEX CarriGen bone void fillers.

Predicate Devices:
The N-Force Fixation System was shown to be substantially equivalent to previously cleared screw devices including Treu Bone Fixation Screws and Pins (K083912) and S&N 4.0mm Cannulated Screws (K993106); the Haig Nail System (K961213 and K991889) which, like the

N-Force Screw, is a fracture fixation device that temporarily serves as a surgical instrument; and the delivery systems used with ETEX Beta-bsm and ETEX CarriGen bone void fillers (K101557).

Substantial Equivalence:
Testing performed on the N-Force Screw indicates that it is substantially equivalent to predicate devices. Mechanical testing of the screw included static three-point bending, torsion, axial pull-out, insertion torque, and extraction torque. Additional testing was performed to demonstrate the substantial equivalence of the N-Force Fixation System to the ETEX recommended instruments with respect to their ability to deliver bone void filler material.

Conclusion
The N-Force Fixation System is substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innovision, Inc.
% Ms. Michelle McDonough
1331 H Steet Northwest, 12th Floor
Washington, District Columbia 20005

JUL 28 2011

Re: K102528
Trade/Device Name: N-Force Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 16, 2011
Received: June 20, 2011

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102528

Device Name: N-Force Fixation System

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102528